K033896

JUN 16 2004

Section E – 510(k) Summary

Date of Submission: December 12, 2003

Establishment Registration

Location

Company Name:	Defibtech, LLC
Address 1:	753 Boston Post Road
Address 2:	Suite 102
City, State, and Zip Code:	Guilford, CT 06437

Contact Information

Name:	Mr. John L. Rogers
Telephone:	(203) 453-6654 x13
Facsimile:	(203) 453-6657

Trade (Proprietary) Name	Defibtech AED with Attenuated Defibrillation/Monitoring Pads
Model Number	DDU-100 with DDP-200P
Common Name	Automatic External Defibrillator with Pediatric Electrodes

Classification

FDA Panel	Cardiovascular
Class	Class III
Regulation	21 CFR 870.1025 - Arrhythmia detector and alarm

Substantial Equivalence

Model	*Manufacturer*	*510(k) Number*
Heartstream Attenuated Defibrillation Pads	Agilent Technologies, Inc.	K003819

Device Description

Defibtech Attenuated Defibrillation/Monitoring Pads are intended for use only with Defibtech DDU-100 Series AEDs or compatible Defibtech AEDs, on patients who are less than eight years of age.

Attenuated Defibrillation/Monitoring Pads are indicated for use on victims of sudden cardiac arrest (SCA) when the patient is:

- Unconscious and unresponsive
- Not breathing
- Less than eight years old

A pulse check is not required based on the recommendations of the American Heart Association Guidelines 2000 for CPR and ECC.

Section E – 510(k) Summary

Only people trained in its use should operate the Defibtech Series AEDs. This may include emergency care personnel specifically trained on Defibtech AED's or one of the following:

- People with training in advanced life support (ALS)
- People with training in basic life support (BLS)
- People filling other physician-authorized emergency medical response role

Defibtech Attenuated Defibrillation/Monitoring Pads must be used by or on the order of a physician.

Attenuated Defibrillation/Monitoring Pads consist of two self-adhesive defibrillation/ monitoring pads used to monitor ECG signals and, if necessary, to deliver defibrillation energy to the patient. Attenuated Defibrillation/Monitoring Pads incorporate an energy attenuator, which cuts the nominal defibrillation energy of a Defibtech Series AED (150 Joules) to 50 Joules. They are provided as a packaged, single-use disposable assembly.

The impedance between the two pads is monitored to ensure proper pad-to-patient contact. Visual and audio prompts inform the operator of possible problems with patient contact. Voice prompts and visual indicators communicate the status of the AED and of the patient to the operator.

Defibrillation energy is delivered as a biphasic truncated exponential waveform. The device delivers 150 Joules into a 50-ohm load. The pads incorporate an attenuator that decreases the energy delivered to the patient to 50 Joules. Delivered energy does not change significantly with patient impedance, although the duration of the generated waveform will vary. The Defibtech Series AED is designed to deliver up to 50J of defibrillation energy through a pediatric patient impedance range of 25 – 175 ohms.

Intended Use
The Attenuated Defibrillation/Monitoring Pads are to be used with Defibtech Series AEDs on victims of sudden cardiac arrest ("SCA") when the patient is:

- Unconscious and unresponsive
- Not breathing
- Less than eight years old

Attenuated Defibrillation/Monitoring Pads must be used by or on the order of a physician.

Do not delay therapy to determine exact age or weight.

Conclusion Summary of Safety and Effectiveness
Testing and performance evaluations demonstrate that the safety and effectiveness of the Attenuated Defibrillation/Monitoring Pads is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 16 2004

Defibtech, LLC
c/o Mr. John L. Rogers
Director Medical Device Compliance
753 Boston Post Rd., Suite 102
Guilford, CT 06437

Re: K033896
Trade Name: Defibtech AED with Attenuated Defibrillation/Monitoring Pads
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: III (three)
Product Code: MKJ
Dated: March 18, 2004
Received: March 19, 2004

Dear Mr Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section D - Statement of Indications of Use

Applicant: Defibtech, LLC

510(k) Number (if known): K033896

Device Name: Defibtech DDU-100 AED with DDP-200P Attenuated Defibrillation/Monitoring Pads

Indications For Use:

The Attenuated Defibrillation/Monitoring Pads are to be used with Defibtech Series AEDs on victims of sudden cardiac arrest ("SCA") when the patient is:

- Unconscious and unresponsive
- Not breathing
- Less than eight years old

Defibtech Attenuated Defibrillation/Monitoring Pads must be used by or on the order of a physician.

Do not delay therapy to determine exact age or weight.

Prescription Use __YES__ AND/OR Over-The-Counter Use __NO__
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

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Number K033896